

B. Rejections Under 35 U.S.C. §102

Claims 1-7 were rejected as being anticipated by Prochazka (U.S. Pat. No. 5,562,707). In addition, claims 1-2 and 4-7 were rejected as being anticipated by Feingold (U.S. Pat. No. 4,871,351).

Prochazka is characterized as disclosing a wrist worn sensor and controller providing functional electrical stimulation to an implanted neuro stimulator and communication of data relating to the pressure of muscular stress as the wrist is flexed. Claims 1 and 6 to are drawn to an apparatus and method, respectively, whereby an implantable medical device (IMD) receives data from an external physiological signal sensor and utilizes the information to initiate, control, modify or program the delivery of therapy or store the data for later follow-up retrieval and diagnostic review of a patient. Contrary to the characterization of Prochazka in the office action, the Prochazka device does not involve an implantable medical device. Instead, the stimulator provides stimulation pulses to muscles using contact pads and electrodes 95. Accordingly, the rejection of claims 1-7 as being anticipated by Prochazka is in error and should be withdrawn.

Feingold discloses an implantable drug delivery system wherein control commands are received from an external controller that is in a feedback loop and operating on the basis of a measured physiological parameter affected by the delivered drug. In Feingold, the system normally functions as an open loop infusion system operating in accordance with pre-programmed profiles and only intermittently accesses a physiological sensor (col. 2, lines 49-56). Feingold does not teach a dynamic closed loop self-monitoring system in continuous communication with an IMD to effect

operational/functional changes in the IMD. Accordingly, the rejection of claims 1-2 and 4-7 as being anticipated by Prochazka is in error and should be withdrawn.

In addition, the rejection of claim 3 as being unpatentable for obviousness based on Feingold and Amano (U.S. Pat. No. 5,941,837) should be withdrawn in view of the distinction of the amended claims over Feingold.

C. Conclusion

Based upon the amendments to the claims, Applicant submits that all pending claims are in condition for allowance and request that a notice of allowance be issued in due course.

Respectfully submitted,

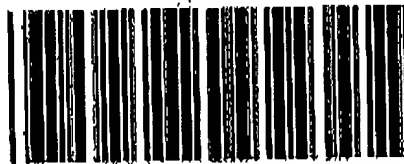
Date: December 27, 2002

By: Girma Wolde-Michael

Girma Wolde-Michael

Reg. No. 36,724

Telephone: (763) 514-6402



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MARKED-UP VERSION OF AMENDED CLAIMS

IN THE CLAIMS:

1. A system for controlling the operations of at least one implantable medical device ("IMD") [IMD] via an external device in data communication[s thereof] with the IMD, the system comprising:
[the] at least one IMD providing therapy delivery;
at least one physiological sensor implemented in [the] an external device; and
means for transmitting [medical data between] control signals to the [at least one] IMD [and] from said external device;
said physiological sensor and transmitting means forming a dynamic closed loop self monitoring system.
2. The system of claim 1 wherein said at least one IMD [includes] is selected from the group consisting of a pacemaker, a defibrillator, a drug pump, and a neuro stimulator [and a combination thereof].
3. The system of claim 1 wherein said external device includes a sensor selected from the group consisting of a wristwatch sensor, a ring sensor, a patch sensor, and an active sock sensor [and a combination thereof].
5. The system of claim 1 wherein said [medical data includes] physiological sensor is one selected from the group consisting of pressure, oxygen saturation, cardiac acceleration, flow sensing, heart auscultations, and intracardiac impedance [and physiological data for use in diagnosis and therapy].
6. A method of controlling the functional and operational aspects of at least one implantable medical device ("IMD") [IMD] via an external device wherein the IMD and the external device [being communicable] are in communication via an operable wireless data communications system to form a dynamic closed loop monitoring system, the method comprising:

[collecting at least one significant] producing an IMD control [medical] signal at [the] an external device based upon a physiological sensor;

transmitting said [medical] control signal to the IMD via [the] a wireless communication data system; and

inducing a responsive action within the IMD upon reception of said [medical] control signal from the external device.

7. The method of claim 6 wherein said responsive action [includes one of and combinations of] is selected from the group consisting of delivery of therapy, implementation of diagnostic procedures and storing [said] of medical data in memory for future reference and follow-up.